UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOT FOR PUBLICATION

IN RE FETZIMA	Civil Action No. 2:17-cv-10230-ES-SCM **OPINION** **ON MOTION TO AMEND** **INFRINGEMENT CONTENTIONS** **[D.E. 175]**

Steven C. Mannion, United States Magistrate Judge.

This matter comes before the Court by way of informal application to amend infringement contentions by Plaintiffs Allergan Sales, LLC, Forest Laboratories Holdings Limited, and Allergan USA, Inc. (collectively, "Allergan").[1] Allergan seeks to supplement their infringement contentions to include certain documents that they assert are new evidence. Defendants Limited and Torrent Pharma Inc. consent to Allergan's amended infringement contentions to the Torrent defendants. Defendants MSN, Aurobindo, Hikma, and Zydus ("MSN Defendants") oppose Allergan's application.[2] For the following reasons, the Court GRANTS in PART and DENIES in PART Allergan's application.

[1] (ECF Docket Entry No. ("D.E.") 175). The Court will refer to documents by their docket entry number and the page numbers assigned by the Electronic Case Filing System.

[2] "Aurobindo" refers to Aurobindo Pharma USA, Inc. and Aurobindo Pharma Limited. MSN refers to MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. Hikma refers to Hikma Pharmaceuticals International Limited and Hikma Pharmaceuticals USA Inc. Zydus refers to Zydus Pharmaceuticals (USA) Inc.

I. BACKGROUND AND PROCEDURAL HISTORY

In October 2017, Allergan commenced several Hatch-Waxman actions for infringement of three patents against Prinston Phamacueitcal, Inc., Solco Healthcare, Aurobindo Pharma Limited, Amneal Phamaceuticals LLC, Amneal Pharmaceuticals Private Limited, Zydus Pharmaceuticals Inc, West-ward Pharmaceuticals International Limited, West-ward Pharmaceuticals Corp, MSN Laboratories Private Limited, MSN Pharmaceuticals Inc., and Torrent Pharmaceuticals Limited and Torrent Pharma Inc (collectively, "Defendants"). Defendants have submitted Abbreviated New Drug Applications ("ANDAs") to the FDA for approval to sell generic versions of levomilnacipran hydrochloride, brand name Fetzima®, before the expiration of the three patents. Fetzima is used for treatment of major depressive disorder.

The actions were consolidated on February 8, 2018. The Court held its Rule 16 conference in March of 2018. Document production was to be produced on a rolling basis with a final deadline of January 10, 2019.[3] On or after the January 2019 document production deadline, Allergan received more than 120,000 documents and 700,000 pages from the Defendants. The MSN Defendants did not request an extension of the January 10, 2019 document production deadline. The MSN Defendants continued to produce documents from January 10, 2019 to July 2019.[4]

[3] (D.E. 34.)

[4] (D.E. 175.)

On June 7, 2019 the Allergan Plaintiffs requested the MSN Defendants' consent to supplement their infringement contentions.[5] On June 10, 2019, the Allergan Plaintiffs requested from the Court an extension of the fact discovery deadline, which was set for June 12, 2019.[6] On June 11, 2019, Allergan informed the Court that it intended to request leave to amend its infringement contentions.[7] At this time, the parties had just begun fact depositions.[8] Allergan seeks to include citations to certain categories of documents that it claims constitute new evidence:

(1) Defendants' documents relating to their analytical testing and manufacturing processes of their accused products;

(2) Defendants' data from additional API lots and exhibit batches of Defendants' accused products;

(3) Transcripts of inventor testimony elicited by Defendants and corresponding deposition exhibits;

(4) Additional supporting pin cites to Defendants' ANDAs, identified in Plaintiffs' July 11, 2018 Infringement Contentions as evidence of Defendants' accused products; and

(5) Corrected document production number errors.

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[5] (D.E. 175.)

[6] (D.E. 157.)

[7] (D.E. 158.)

[8] (*See* D.E. 157.)

Between May 30 and June 21, 2019, Defendants noticed and took depositions of three named inventors of the asserted patents, i.e., Anil Chhettry, Murali Divi, and Mahendra Dedhiya.

On June 18, 2019, July 8, 2019, and July 12, 2019, Aurobindo, MSN, and Zydus consented to Plaintiffs' supplementation of certain documents.[9] Some of these documents were produced on May 30, 2019.[10]

On July 22, 2019, the Court extended the fact deposition deadline to August 30, 2019.[11] A Markman Hearing was held in September of 2019. In October of 2019, the Court extended deadlines for opening expert reports to January 13, 2020 and set completion of expert discovery for May 15, 2020.

The Court heard oral argument on the instant motion to amend infringement contentions on November 19, 2019. During oral argument, the parties represented that they had no issue with allowing the amendments to include documents in category 5, i.e., corrected document production number errors. In response to the Court's questions at its oral argument on the pending motion, on December 20, 2019, the parties submitted supplemental information detailing the dates of production of various documents.[12]

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[9] (D.E. 175, Ex. 8.)

[10] (*See* D.E. 175, Ex. 3)

[11] (D.E. 180.)

[12] (D.E. 228).

II. MAGISTRATE JUDGE AUTHORITY

Magistrate judges are authorized to decide any non-dispositive motion designated by the Court.[13] This District specifies that magistrate judges may determine all non-dispositive pre-trial motions which includes discovery motions.[14] Decisions by magistrate judges must ordinarily be upheld unless "clearly erroneous or contrary to law,"[15] but where the decision concerns a non-dispositive matter such as a discovery dispute, the ruling "is entitled to great deference and is reversible only for abuse of discretion."[16]

III. LEGAL STANDARD

Leave to amend non-infringement contentions may be granted "by order of the Court upon a timely application and showing of good cause."[17] There must also be no undue prejudice to the adverse party.[18]

The Local Patent Rules are "designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed."[19] In

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[13] 28 U.S.C. § 636(b)(1)(A).

[14] L. CIV. R. 72.1(a)(1); 37.1.

[15] 28 U.S.C. § 636(b)(1)(A).

[16] *Kresefky v. Panasonic Commc'ns and Sys. Co.*, 169 F.R.D. 54, 63-64 (D.N.J. 1996); *Cooper Hosp./Univ. Med. Ctr. v. Sullivan*, 183 F.R.D. 119, 127 (D.N.J. 1998).

[17] D.N.J. Local Patent Rule 3.7.

[18] *Jazz Pharms., Inc. v. Roxane Labs., Inc.*, No. 10-6108, 2013 WL 785067, at *4 (D.N.J. Feb. 28, 2013).

[19] *TFH Publications, Inc. v. Doskocil Manufacturing, Co., Inc.*, 705 F.Supp.2d 361, 365-66 (D.N.J. 2010) (citing *Atmel Corp. v. Info. Storage Devices, Inc.*, 1998 WL 775115, at *2 (N.D.Cal. Nov. 5, 1998)).

contrast to the liberal standard for amending pleadings, "the philosophy behind amending claim charts is decidedly conservative, and designed to prevent the 'shifting sands' approach to claim construction."[20] In the District of New Jersey, the Local Patent Rules emphasize the "ultra early disclosure of infringement and invalidity contentions for patent cases arising under the Hatch-Waxman Act."[21]

It should be noted, however, that Rule 3.7 "is not a straightjacket into which litigants are locked from the moment their contentions are served."[22] Instead, "a modest degree of flexibility [exists], at least near the outset" of litigation.[23] Accordingly, it is important to recognize that while the Local Patent Rules strive to encourage parties to establish their contentions early on, "preliminary infringement contentions are still preliminary."[24]

With regard to the "good cause" requirement of Rule 3.7, the Federal Circuit has stated that parties must "proceed with diligence in amending when new information comes to light in the course of discovery."[25] "Good cause considers first whether the moving party was diligent in amending its contentions and then whether the non-moving party would suffer prejudice if the

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[20] *Id.* (quoting *Atmel Corp.*, 1998 WL 775115, at *2); *see also King Pharmaceuticals, Inc. v. Sandoz, Inc.*, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010).

[21] *Sanofi-Aventis v. Barr Labs., Inc.*, 598 F.Supp.2d 632, 637 (D.N.J. 2009).

[22] *Comcast Cable Communs. Corp. v. Finisar Corp.*, 2007 WL 716131, at *2 (N.D.Cal. March 2, 2007).

[23] *Id.*

[24] *TFH Publications, Inc.*, 705 F.Supp.2d at 366 (quoting *General Atomics v. Axis-Shield ASA*, 2006 WL 2329464, at *2 (N.D.Cal. Aug. 9, 2006)).

[25] *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1366-68 (Fed. Cir. 2006).

motion to amend were granted."[26] The party seeking to amend bears the burden of establishing diligence.[27] Moreover, a party must not only prove that it was diligent in seeking leave to amend, but also prove that it was diligent in discovering the basis for the proposed amendment.[28] Courts have considered several factors in determining whether good cause exists: "(1) the reason for the delay, including whether it was within the reasonable control of the party responsible for it; (2) the importance of what is to be excluded; (3) the danger of unfair prejudice; and (4) the availability of a continuance and the potential impact of a delay on judicial proceedings."[29]

IV. DISCUSSION AND ANALYSIS

A. Amendments relating to analytical data documents

The Court will first consider whether the Allergan Plaintiffs should be permitted to amend their infringement contentions to include certain documents pertaining to analytical data.[30] The Court finds that the Allergan Plaintiffs have demonstrated good cause to amend their infringement contentions to include the analytical data documents that the MSN Defendants did not produce until on or after the document production deadline of January 10, 2019. These documents are identified in the parties' joint chart as AUROBINDO Doc Nos. 5-16; HIKMA Doc Nos. 9-20;

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[26] *Celgene Corp. v. Natco Pharma Ltd.*, 2014 WL 6471600, at *2 (Nov. 18, 2014) (internal citations and quotations omitted).

[27] *Id.* at 1366; *Jazz Pharms., Inc. v. Roxane Labs.*, Inc., 2013 U.S. Dist. LEXIS 28374, at *7 (D.N.J. Feb. 28, 2013) (citing *West v. Jewelry Innovations, Inc.*, 2008 U.S. Dist. LEXIS 84928, at *1 (N.D.Cal. Oct. 8, 2008)).

[28] *Id.*

[29] *LMT Mercer Group, Inc. v. Maine Ornamental, LLC*, No. 10-6699(FLW), 2014 WL 284238 (Jan. 24, 2014) (internal citations omitted).

[30] The parties represented during oral argument that documents relating to analytical testing data would refer to those documents identified as categories 1, 2, and 4 in the Allergan Plaintiff's letter (D.E. 175) as well as in the Factual Background section of this opinion.

MSN Doc Nos. 5-11; ZYDUS Doc Nos. 7-14; and FOREST Doc Nos. 9-11.[31] The Court finds that the Allergan Plaintiffs do not demonstrate good cause to amend to include documents that were produced before January 10, 2019.

In assessing the reason for the Allergan Plaintiff's delay, including whether it was within the reasonable control of the party responsible for it, the Court finds that this factor supports allowing the Allergan Plaintiffs to add the documents produced on or after January 10, 2019. The Court provided approximately 9 to 10 months for Defendants to produce documents on a rolling basis. But Defendants produced the vast majority of the documents at the end. The MSN Defendants do not deny that the Defendants altogether produced approximately 700,000 pages on the deadline.[32] And they continued to produce. The MSN Defendants failed to seek from the Court an extension of time to complete document production from the Court, produced several documents late, and now seek to preclude the Allergan Plaintiffs from including those documents in their infringement contentions on the grounds that the Allergan Plaintiffs are belatedly seeking to amend.

The Court finds that it was within the reasonable control of the MSN Defendants to produce more documents earlier in the process. These documents were in their control and possession, and their position that it should be a quick task to review production does not correspond with their delay in taking nearly 10 months to produce that production. If document review is as simple a matter as the MSN Defendants assert,[33] then the majority of the documents should have been

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[31] *See* Joint Chart (D.E. 228).

[32] *See* D.E. 184; Def's brief at 4, n. 2 (arguing that only a small fraction of 700,000 pages were produced late, but not denying that upwards of 700,000 pages were produced on or after the January 10, 2019 deadline).

produced well in advance of the document production deadline, and not on or after it. While Defendants' production on the last day of production was technically on time, the analysis does not focus solely on which party was late, but considers which party had reasonable control over the ultimate delayed infringement contentions. Here, the Court finds that had Defendants produced the bulk of their documents earlier in the process, then the Allergan Plaintiffs would have been able to seek to amend infringement contentions earlier in the process as well.

The Court finds that the Allergan Plaintiffs were reasonably diligent in seeking leave to amend to include those documents produced on or after January 10, 2019. Litigating this case, complying with all of the deadlines, and the process of reviewing and gathering documents was a process that took nearly 10 months for the Defendants to complete. The Court finds that the Allergan Plaintiffs were diligent in raising the issue of amending its contentions in less than four months from obtaining 700,000 pages of scientific documents. During this time, the Allergan Plaintiffs had to continually review new documents that Defendants were producing beyond the production deadline, consider incorporating them into their infringement contentions, meet February deadlines for claim construction briefs, and prepare for the inventor depositions. The Court finds that in this multi-defendant case with many moving parts, the Allergan Plaintiffs were reasonably diligent in seeking leave to amend shortly after obtaining the documents they seek to include. Indeed, in this district, a court found that amendments to invalidity contentions were timely when the amending party took less than four months to review the other side's 544 page response to their initial invalidity contentions.[34] The three to four month period was not considered

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[33] The MSN Defendants suggest that it should only take a month to review a voluminous complete production. See D.E. 184.

[34] *Abraxis BioScience, LLC v. Actavis, LLC*, No. 16-1925(JMV), 2017 WL 2079647, at *4 (D.N.J. May 15, 2017).

untimely in light of the fact that the party had to "investigate, prepare and serve amended contentions, all while complying with other deadlines in the scheduling order and in light of the practical delays of the Holiday season."[35]

The Court also finds that there will be no unfair prejudice resulting from these limited amendments. In considering unfair prejudice, the Court considers whether the proposed amendment would "(1) require the opposing party to expend significant additional resources; or (2) significantly delay resolution of the dispute."[36] The Court notes that while the MSN Defendants claim they will be prejudiced by the amendment, they fail to identify any specifics. They only state generally that they may need to alter their strategies and allocate resources to address the new documents, and that the Allergan Plaintiffs did not seek to amend until shortly before discovery closed. At least one court in this district has found that general arguments regarding unfair prejudice based on redeveloping strategy are unconvincing and that "a minor adjustment in the current trial schedule would mitigate" any potential prejudice.[37]

While there may be some additional work that needs to be done to address the new citations, the Court does not find that the MSN Defendants will have to expend significant additional resources. Additional work does not mean there is unfair prejudice.[38] Denial of leave to amend requires that the additional work required be substantial or undue."[39] Here, the Court

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[35] *Id.*

[36] *Amgen Inc. . Kashiv Biosciences, LLC*, No. 18-3347 (CCC), 2019 WL 5445974, at *3 (citing *TFH Publications, Inc. v. Doskocil Mfg.*, 705 F.Supp.2d 361, 366 (D.N.J. 2010).

[37] *See AstraZeneca v. Hanmi*, No. 11-760(JAP), 2013 WL 264609, at *2 (D.N.J. Jan. 23, 2013).

[38] *See id.*

[39] *See AS Am, Inc. v. Masco Corp. of Ind.*, 2013 WL 4084237, at *3 (D.N.J. Aug. 13, 2013).

finds that any additional work required will not be substantial or undue because the amendments do not alter the infringement theories, and the parties agree that the amendments would not impact claim construction.[40] Unlike the cases cited by the MSN Defendants, *i.e.*, *O2 Micro* and *Jazz Pharmaceuticals*,[41] in which the parties sought to alter invalidity or infringement theories, here, the Allergan Plaintiffs are not seeking to alter their underlying infringement theories. The MSN Defendants also will not suffer any unfair surprise or prejudice as these are their own documents and they are presumably familiar with them. To avoid any unfair prejudice, the Court will allow the MSN Defendants to amend their invalidity contentions within 21 days to address these amendments.

Finally, the Court finds that these amendments will not significantly delay resolution of this dispute. The MSN Defendants do not cite specifically to any new discovery they will need to undergo because of these amendments.[42] At the time that the Allergan Plaintiffs requested leave to amend, the parties had not even completed fact depositions. In addition, to the extent they will need to tailor expert discovery to the amendments, the expert discovery deadline is not set to expire until May 2020. Unlike the *Antonious v. Nike* case cited by the MSN Defendants, in which the Plaintiff sought to amend its infringement contentions on the eve of the summary judgment deadline, here, the Allergan Plaintiffs sought to amend before fact discovery closed, and there are

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[40] (*See* D.E. 175.)

[41] *O2 Micro Intern v. Monolithic Power Systems*, 467 F.3d 1367 (Fed. Cir. 2006); *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, no. 10-5108(ES-CLW), 2012 WL 3133943 (D.N.J. July 30, 2012).

[42] In addition, the Allergan Plaintiffs claim that Defendants could not articulate any additional fact discovery they would seek from Plaintiffs. (*See* D.E. 175, Ex. 1.)

still several months before expert discovery will close.[43] Taking all factors into account, the Court finds that these amendments will not cause any significant delay to resolution of the case.

B. Amendments relating to inventor depositions

The Court will next consider whether the Allergan Plaintiffs should be permitted to amend their infringement contentions to include documents relating to depositions of the inventors. The Allergan Plaintiffs seeks to cite to transcripts of inventor testimony elicited by Defendants and corresponding deposition exhibits. The depositions were taken between May 30 and June 21, in accordance with the Court's scheduling order. Allergan seeks to supplement its infringement contentions to add the May 30, 2019 deposition transcript of Anil Chhettry and the June 7, 2019 deposition transcript of Murali Divi.

The Court finds that there is no good cause for this late amendment. The Allergan Plaintiffs could have spoken to their own inventors and discerned the nature of their testimony much earlier in the case, as they were putting together their infringement contentions, and tailored their infringement contentions accordingly. Similarly, the Allergan Plaintiffs had the opportunity to review the deposition exhibits as these have been in their possession and were documents they themselves produced at deposition. Because the Court does not find good cause for this late amendment, it will deny this amendment.

C. Other Amendments

Finally, the Court will allow the Allergan Plaintiffs to amend their infringement contentions to add corrected document production numbers. At oral argument, the parties represented that they did not oppose amendments concerning typographical errors.

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[43] *See Antonious v. Nike*, 2015 WL 6122457 (D.N.J. Oct. 10, 2015).

Subsequently, in their latest joint letter to the Court, the parties refer to Bates numbering errors and vendor errors. The Court will allow the amendments referred to in the joint letter as a bates numbering correction (i.e., AGNPF01330777-81), as well as the amendments concerning a vendor error (i.e., AGNPF01331112-202 and AGNPF01331112-202).

An appropriate Order follows:

ORDER

IT IS on this Tuesday, January 28, 2020,

1. **ORDERED**, that the Allergan Plaintiffs' motion to amend infringement contentions is **GRANTED** in part and **DENIED** in part; and it is further
2. **ORDERED**, that the Allergan Plaintiffs' motion to amend infringement contentions to add the documents identified as AUROBINDO Doc Nos. 5-16, HIKMA Doc Nos. 9-20, MSN Doc Nos. 5-11, ZYDUS Doc Nos. 7-14, and FOREST Doc Nos. 5, 10, 11 is GRANTED; and it is further
3. **ORDERED**, that the Allergan Plaintiffs' motion to amend infringement contentions to add the remaining documents identified in the chart at D.E. 228 is **DENIED**; and it is further
4. **ORDERED**, that the Allergan Plaintiffs' motion to amend infringement contentions to add inventor deposition transcripts and exhibits is **DENIED**; and it is further
5. **ORDERED,** should the MSN Defendants wish to amend their invalidity contentions to address

the Allergan Plaintiffs' amendments, they must do so within 21 days.

Steven C. Mannion

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cc: All parties
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